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IN THE

Supreme Court of the United States

OCTOBER TERM, 1952

No. 610

ATLAS POWDER COMPANY, a Corporation,
Petitioner,

v.

OSCAR R. EWING, Federal Security Administrator,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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ATLAS POWDER COMPANY, a Corporation,
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OSCAR R. EWING, Federal Security Administrator,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Petitioner prays that a Writ of Certiorari issue to review the judgment of the United States Court of Appeals for the Third Circuit, entered in the above-entitled case on December 22, 1952.

OPINIONS BELOW

The order and memorandum opinion of the Respondent, Federal Security Administrator, are reported in 17 Fed. Reg. 4453, 4467 (R. 458, 476). The opinion of the Court of Appeals (R. 3283) is not yet reported.

JURISDICTION

The judgment of the Court of Appeals was entered on December 22, 1952. A petition for rehearing was denied on January 14, 1953. The jurisdiction of this Court is invoked under 28 U. S. C. 1254(1).

QUESTIONS PRESENTED

1. Whether Congress intended, by Section 401 of the Food, Drug, and Cosmetic Act, to empower the Federal Security Administrator to banish an established ingredient from a standardized food on the negative finding that he could not conclude that there is no likelihood of injury from the use of the ingredient when consumed over a life span.

2. Whether an administrative finding essential to the validity of a purported distinction between two fundamentally similar and competing food ingredients, invoked to permit the use of one ingredient in a standardized food and to exclude the other, may be made as a matter of administrative judgment without *any* supporting evidence.

3. Whether a Court of Appeals may deny a request for leave to adduce additional evidence under Section 701(f)(2) of the Food, Drug, and Cosmetic Act without independently determining the materiality of the evidence so offered.

STATUTE INVOLVED

The pertinent provisions of the Food, Drug, and Cosmetic Act are printed in Appendix A, *infra*.

STATEMENT OF THE CASE

Petitioner, Atlas Powder Company, manufactures a food ingredient which has been widely marketed to the baking trade under the name of Myrj 45. Myrj 45 is an "emulsifier"—a substance which helps dissimilar materials such as oil and water to mix with each other. Myrj 45 in commercially baked white bread keeps the bread softer for a longer period of time than would otherwise be the case (R. 742). This ingredient was introduced for use in bread in 1947 after years of research by Atlas and others engaged in the field of food technology (R. 733, 748). The object widely sought was to provide a loaf of bread for the consumer which would stay soft and palatable for as long as possible after baking, thus prolonging the life of the bread, and reducing economic waste. For several years before the introduction of our product bakers had used other products, including a type known as mono- and diglycerides, to achieve the same result (R. 674-675, 753). The introduction of our type of product early in 1947 met with widespread acceptance among bakers (R. 2786, 2811, 2828, 2890-2891) and it very soon began to make deep inroads on the market previously enjoyed by the producers of mono- and diglycerides.

In 1948, the Federal Security Administrator* resumed a series of hearings which were begun in 1941 and were designed to fix definitions and standards of identity for commercially baked white bread, under Section 401 of the Food, Drug, and Cosmetic Act, *infra*, p. 4a. Once such a standard has been promulgated for a food, it becomes

*The administration of the Food, Drug, and Cosmetic Act was transferred from the Secretary of Agriculture to the Federal Security Administrator by Reorganization Plan IV, section 12, set out in note to Section 133t of Title 5, U. S. C. (1946).

unlawful to sell that food in interstate commerce if it contains an ingredient not specifically permitted by the standard. Under the hearing procedure employed by the Federal Security Administrator, anyone who wishes to have a particular ingredient included in a food standard appears at the hearing and presents evidence about the ingredient's use in the particular food. All other persons who appear at the hearings, whatever their purpose, enjoy a virtually unlimited right of cross-examination. Atlas presented witnesses in support of the suitability of Myrj 45 for use in bread. Atlas' competitors extensively cross-examined these witnesses in an attempt to discredit the use of Myrj 45 in bread (*e. g.*, R. 1316-1358). In addition, some of these competitors introduced witnesses of their own who presented opinion evidence as to the alleged unsuitability of Myrj 45 (*e. g.*, R. 2906-2936).

The hearings closed on September 20, 1949. On August 8, 1950, the Administrator promulgated a proposed order, excluding Myrj 45 as an optional ingredient in bread at any level. The Administrator based his tentative exclusion of Myrj 45 on the two grounds that:

> (a) Its use at any level tends to deceive consumers by making them think that the bread in which it is used is not so old as it actually is (R. 14); and
>
> (b) Although "there has been no definite evidence of injury" from the use of Myrj 45 and other Atlas products in bread,* "the investigational work does

*Petitioner proposed several emulsifiers manufactured by it for inclusion as optional ingredients in bread. This review proceeding concerns only Myrj 45, the principal Atlas emulsifier sold for use in bread.

not definitely establish their safety, and the record does not permit a conclusion that bread containing them is safe for continuous use over the human life span" (R. 15).

The Administrator failed to make any tentative findings on either of these two issues as to the competing mono- and diglycerides. Nevertheless, his proposed order admitted them to the standard at a maximum level of 25% of the shortening content of bread (R. 5-6).

In October, 1950, Atlas filed a motion to re-open the record, pointing out the Administrator's failure to apply similar criteria to the competing mono- and diglycerides, and offering new evidence to show that the two classes of products were comparable in all essential respects relating to the issues of safety and deception (R. 19). From time to time thereafter, Atlas supplemented its motion to re-open with further offers of proof (*e.g.*, R. 177, 201, 210, 284, 389). It also requested that the hearing be re-opened to receive as evidence tests conducted by Food and Drug Administration scientists on the suitability of Myrj 45 (R. 347).

On May 15, 1952, the Administrator published a memorandum opinion denying Atlas' motion to re-open the record (R. 476). At the same time, he published his final order prescribing definitions and standards of identity for bread (R. 458).

The Administrator's final order excluded Myrj 45 on substantially the same "safety" and "deception" considerations as underlay his 1950 order (R. 14, 15, 472, 473). The same order excluding Myrj 45 from the food standard admitted the competing mono- and diglycerides.

The Administrator's final order differed from his proposed order in several respects. The final order reduced

the permitted level of mono- and diglycerides to 20% of the shortening content. The Administrator admitted that the 25% level set in the tentative order might cause deception "such as sometimes occurs" when Myrj 45 is used (R. 460, 461), but found that the 20% level would be non-deceptive (R. 461). He also conceded in his final finding that certain safety aspects of the mono- and diglycerides (their surface-active effects before digestion) "have not been adequately investigated to permit a final decision that they are safe for use in bread which is regularly consumed in a life span" (R. 468). He nevertheless permitted the continued use of mono- and diglycerides pending a re-opened hearing at some time in the future at which evidence of their safety could be considered (R. 473A). But he refused Myrj 45 continued access to the market. He excluded it on the combined grounds of deception and safety. On safety he found that "there was no definite evidence of injury" from the use of Myrj 45 in bread, but he excluded it from use in bread on the negative finding that:

> "the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed to persons consuming it continuously over a life span" (R. 473).

On May 22, 1952, Atlas sought review of the Administrator's order in the Court of Appeals for the Third Circuit (R. 3234). Atlas requested that Court to set aside the Administrator's order and to exercise its statutory function under Section 701(f)(2) of the Food, Drug, and Cosmetic Act of directing the Administrator to receive pertinent additional evidence which had developed since the close of the

hearings in September 1949 (R. 3234, 3249). At the same time, Atlas also applied for a stay of the Administrator's order (R. 3252). Following oral argument and the consideration of briefs submitted by both parties, the Court of Appeals, on June 10, 1952, granted a stay (R. 3282), which remains in effect until the conclusion of the review proceedings.

On December 22, 1952, the Court of Appeals affirmed the Administrator's order (R. 3299). It approved the Administrator's exclusion of Myrj 45 from the bread standard on the negative finding that Atlas had not proven that there was no likelihood of injury from its use over a life span (R. 3294).* The Court also held that the Administrator could lawfully eliminate Myrj 45 as deceptive and at the same time include the mono- and diglycerides by setting a "non-deceptive" level for their use simply as a matter of administrative judgment and without evidentiary support (R. 3295). Finally, the Court, without making its own independent determination, accepted the Administrator's conclusion that the results of tests on the safety of Myrj 45 conducted in the Food and Drug Administration's own laboratories since the close of the hearings in 1949 did not constitute material additional evidence (R. 3297-8).

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*The Court's handling of the two prime issues of safety and deception shows that its error on either issue is a sufficient ground, standing alone, for reversal of its decision approving the Administrator's action. The Court of Appeals has stated that "risk of injury to health and risk of deception as to bread age were *both* relevant matters before the Administrator, and *the combined weight of proper findings in both regards led to the exclusion of petitioner's products*" (R. 3296, emphasis supplied).

REASONS FOR GRANTING THE WRIT

I.

By ruling that Congress authorized the Federal Security Administrator, in promulgating a standard of identity for food, to banish an established food ingredient from the market on a negative finding that the record did not justify its continued use—rather than an affirmative finding that the record justified its banishment—the Court of Appeals decided a novel and important question of Federal law which has not been, but should be, resolved by this Court.

A. Importance of the Question.

The Court of Appeals has rendered an important and far reaching decision about the extent of the power conferred by Congress to banish an established food ingredient from the market by administrative action establishing standards of identity.

In this case the Federal Security Administrator ruled that although "the record shows no definite evidence of injury" from the use of Myrj 45 and related Atlas products in the amounts in which they are likely to occur in bread, "the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed to persons consuming it continuously over a life span" (R. 473). On the strength of this negative finding*

*This negative finding differs materially from the finding at issue in *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218, 220 (1943) where the Administrator supported his order by the *affirmative* finding that Quaker Oats enriched farina "would tend to confuse and mislead." See also *F. T. C.* v. *Morton Salt Co.*, 334 U. S. 37 (1948).

the Administrator eliminated the petitioner's products from a market which they had enjoyed since 1947.*

If the Administrator has this power, he can banish an established ingredient from the market without any evidence at all showing affirmatively that there is reasonable likelihood of injury from the ingredient's use. Instead he can impose on food producers "the inherently impossible" task of trying to prove the negative that there is no likelihood of injury. *Cf. Anniston Manufacturing Co.* v. *Davis*, 301 U. S. 337, 352-354 (1937). Such a difference in the measure of proof, "as every lawyer knows, is not unimportant and in many cases would be decisive." *Cf.* Jackson, J. dissenting in part in *F. T. C.* v. *Morton Salt Co.*, 334 U. S. 37, 55, 56 (1948).** No matter how much testing a food producer may do, it would be virtually impossible to prove, for example, that there is no likelihood of injury from use in foods of salt, flour, or Myrj 45 because it cannot be proven that there is no likelihood that they do not have some

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*The administrative action under review here affects the use of our products in commercially baked white bread and rolls only. Our products will continue to be used in other foods for which no standards have yet been established.

**A dramatic illustration of the effect of a slight difference in the measure of proof is the difference between the Executive Orders outlining the responsibility of the President's loyalty boards. An order promulgated in 1947 authorized dismissal of Federal employees where there were "reasonable grounds . . . for belief that the person involved is disloyal." Executive Order No. 9835, 12 Fed. Reg. 1935, 1938 (1947). In 1951 this order was amended to authorize dismissal where there was a "reasonable doubt" as to loyalty. Executive Order No. 10241, 16 Fed. Reg. 3690 (1951). The difference between these standards is not so sharp as the difference between an affirmative and a negative finding. Yet the substantial effect of this change in the measure of proof is shown by the fact that within six months after the amendment of the Executive Order, the Loyalty Review Board announced that 565 cases which had been decided under the old standard were ordered reopened for review in the light of the new standard. U. S. Civil Service Commission Press Release, December 17, 1951.

relationship to multiple sclerosis or cancer, since all of the causes of these diseases are not known. It would take decades to set at rest the hundreds of questions that can be asked about any food or food ingredient—questions which may be motivated by honest scientific doubts or by the desire of entrenched competitors to preserve their competitive advantages. Atlas and other producers of food ingredients already spend large amounts on the difficult and time-consuming experiments required to test the safety of their products. If the additional burden of proving a negative is to be placed on producers of new and useful ingredients, Congress, not the Administrator, should make the decision to impose that burden.

Moreover, the power to act on the basis of a negative finding virtually deprives food producers of their right to a "high degree of judicial review,"* and prevents appellate courts from exercising their statutory duty to insure that the Administrator's findings are supported by substantial evidence. *Cf. Phelps-Dodge Corp.* v. *N. L. R. B.*, 313 U. S. 177, 197 (1941); see also *S. E. C.* v. *Chenery Corp.*, 318 U. S. 80 (1943). If the Administrator merely has to say to a food producer, "You have not convinced me that there is no likelihood of harm from your product," there is no effective way in which a Court can measure the conclusion against the supporting evidence. It is virtually impossible, for example, to make an intelligent judicial review of the Administrator's distinction between mono- and diglycerides and Myrj 45, when he admitted the former and excluded

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*See Fuchs, *The Formulation and Review of Regulations Under the Food, Drug, and Cosmetic Act*, 6 LAW AND CONTEMPORARY PROBLEMS 43 (1939).

the latter on negative findings as nearly identical as the two quoted below:

> *Mono- and Diglycerides.*
>
> "their surface-active effects before digestion have not been adequately investigated to permit a final decision that they are safe for use in bread which is regularly consumed in a life span" (R. 468).
>
> *Myrj 45.*
>
> "the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed to persons consuming it continuously over a life span" (R. 473).

This vast unreviewable power would extend to every ingredient in foods which the Administrator determined to standardize, whether the food ingredient be old or new, natural or chemical, agricultural or industrial.

The novel question here is whether Congress intended to confer this kind of power upon the Administrator in a food standard proceeding. We contend that Congress did not. In his "anxiety to effectuate the congressional purpose of protecting the public" the Administrator has extended "the scope of the statute beyond the point where Congress indicated it would stop," *cf. 62 Cases of Jam* v. *United States,* 340 U. S. 593, 600 (1951), and has persuaded the Court of Appeals to approve the extension. We submit that a determination of such far reaching implications deserves a plenary review by this Court.

B. The food standard statute authorizes banishment of an established food ingredient only on an affirmative finding that the ingredient is unsuitable—not a negative finding that suitability has not been proved.

The Administrator acted here under the authority of Section 401 of the Federal Food, Drug, and Cosmetic Act of 1938. This section provides, in applicable part:

> "Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food . . . a reasonable definition and standard of identity . . ."

This section is supplemented by Section 701(e) which affords a hearing to any interested person and requires that a food standard order be based "only on substantial evidence of record at the hearing." Section 701(e) further requires the Administrator to set forth as part of the order "*detailed* findings of fact on which the order is based." (Emphasis supplied.) Section 701(f)(1) gives to any person adversely affected by the standard the right to judicial review by a Court of Appeals, provided that "the findings . . . as to the facts, if supported by substantial evidence, shall be conclusive." When a food standard so adopted and approved becomes effective without including a particular product, interstate sale of a standardized food containing that product immediately becomes illegal, no matter how long the product has been used in that food. Sections 301, 303, 403(g).

The language of Sections 401 and 701 and their legislative histories do not even intimate that Congress intended to grant to the Administrator the sweeping power to

eliminate a product already in food on a negative finding that its suitability has not been proven, rather than an affirmative finding that its unsuitability has been proven. Analysis of "the structure of the statute, and the relation, physical and logical, between its several parts" shows that Congress did not intend to give this broad power in the food standard provision. *Cf. Duparquet Huot & Moneuse Co.* v. *Evans,* 297 U. S. 216, 218 (1936).

The clearest demonstration of the limits on the Administrator's powers appears by a comparison of the food standard provision (Section 401), which does not specifically authorize negative findings, and the new drug provision (Section 505), which does. Both of these provisions were enacted at the same time as part of an integrated and comprehensive scheme for federal supervision of the food, drug, and cosmetic industries.

Congress after full and careful consideration specifically gave the Administrator the power to exclude *new drugs* on a negative finding. In order to prevent the sale and consumption of new drugs until they have been thoroughly tested, Section 505 of the Act provides that no new drug may be sold or used until it has first been approved by the Administrator. And the new drug section specifically authorizes the refusal of an application upon a negative finding. For example, a new drug application may be refused approval because the Administrator determines that "he has insufficient information to determine whether [it] is safe." Section 505(d)(4). See also Sections 505(d)(1), (2) and (3).

Congress after long and extensive hearings and careful thought realized the far reaching implications of its grant of power to act on a negative finding in the new drug

section.* It therefore specifically limited the circumstances in which a negative finding can be used. Congress expressly provided that drugs lawfully on the market before 1938 cannot be removed at all by administrative action.** Pre-1938 drugs can be removed only in a civil or criminal court proceeding in which the Administrator has the burden of proving beyond a reasonable doubt or by a preponderance of the evidence an *affirmative* harmfulness or tendency to harm, or an *affirmative* deception or tendency to deceive. Once a new drug application has been approved, it may be suspended only if the Administrator *affirmatively* finds that the drug is "unsafe" or that the application was originally granted in reliance on a material misstatement. Section 505(e). And such an affirmative finding that an approved drug is "unsafe" can be the basis for suspension of such approval only where lack of safety is shown by new testing methods or by testing methods not deemed reasonably applicable when the application became effective. *Ibid.* These strict limitations on the use of negative findings in the new drug provisions show that Congress would not have authorized their use by silence in the provisions of the Act relating to foods.

The new drug section requires an Executive license before a new drug can be used, and authorizes refusal of a license on the basis of a negative finding. The food standard

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*The Food, Drug, and Cosmetic Act was the product of the deliberation of several Congresses. The legislative history is collected in DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT (1938).

**The Act excluded from the new drug definition any drugs if, before the enactment of the 1938 Act, they were subject to the provisions of the 1906 Pure Food and Drug Act and if thereafter their labeling contained the same representations concerning the conditions of their use. Section 201(p). The 1906 Act contained provisions authorizing civil and criminal action against adulterated and misbranded drugs. 34 Stat. 768, *et seq.* (1906), 21 U. S. C. former sections 1-5, 7-15.

section does not require an Executive license before an ingredient can be used; it authorizes the Executive to banish a use already going on. It does not purport to authorize banishment on a negative finding, and no such authority can properly be implied. This conclusion is reinforced by comparison of the new drug provision analyzed above with the elaborate provisions of the Act specifically concerned with food. Sections 302, 303 and 304 authorize the Administrator to bring civil and criminal actions based on the substantive provisions of Sections 402 and 403 to banish from the market foods which are likely to injure consumer health or likely to cause deception of consumers.* It is significant that Congress required the Administrator in these cases to prove affirmatively at least a likelihood of injury or deception. He could not succeed in a court action merely because a defendant had failed to prove a likelihood of "no injury" or a lack of deception, even where he was acting under provisions primarily and specifically concerned with deception and safety. See *United States* v. *Lexington Mill & Elevator Co.*, 232 U. S. 399 (1914).

These are the basic statutory provisions authorizing the Administrator to act with respect to foods. They authorize banishment from the food supply only by a court. They require an affirmative finding that the banned product is likely to harm or deceive.

In addition, Congress adopted the food standard provision of Section 401, to implement the Administrator's power to bring court actions against food producers who sold things which were not what they purported to be. The power to establish standards of identity was granted primarily to protect the public against deception and was not

*Technically, of course, actions are brought in the name of the United States by the Department of Justice.

addressed primarily to food safety. The section speaks of promoting "honesty" and "fair dealing" and its legislative history shows clearly Congress' primary concern with the economic integrity of food.* But even if safety considerations were relevant under Section 401, that Section does not authorize the Administrator to act on a negative finding any more than do the provisions which specifically authorize court action against unsafe or deceptive foods. As we have shown, where the Congress intended to authorize administrative action on the basis of a negative finding, as in the new drug provision *adopted at the same time as part of the same statute,* it clearly provided for that action. Only an unwarranted construction of Section 401 could authorize

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*The House Committee Report on Section 401 was as follows:

"Section 401 provides much needed authority for the establishment of definitions and standards of identity and reasonable standards of quality and fill of container for food. One great weakness in the present food and drug law is the absence of authoritative definitions and standards of identity except in the case of butter and some canned foods. The Government repeatedly has had difficulty in holding such articles as commercial jams and preserves and many other foods to the time-honored standards employed by housewives and reputable manufacturers. The housewife makes preserves by using equal parts of fruit and sugar. The fruit is the expensive ingredient, and there has been a tendency on the part of some manufacturers to use less and less fruit and more sugar.

"The Government has recently lost several cases where such stretching in fruit was involved because the courts held the well-established standard of the home, followed also by the great bulk of manufacturers, is not legally binding under existing law. By authorizing the establishment of definitions and standards of identity this bill meets the demands of legitimate industy and will effectively prevent the chiseling operations of the small minority of manufacturers, will in many cases expand the market for agricultural products, particularly for fruits, and finally will insure fair dealing in the interest of the consumer."

H. R. Rep. 2139, 75th Cong., 2d Sess. (1938).

the Administrator to banish an ingredient on a negative administrative finding about safety, when he cannot even get a Court to act on the basis of such findings under the sections of the Act dealing primarily with food safety or the sections dealing primarily with deception in food.

Analysis of the statutory scheme reveals that where Congress meant the Administrator to have the authority to exclude an item from commerce on a negative finding, it considered the question with great care and specifically gave him that authority. The absence of that authority in connection with the food standards provision is conspicuous. This Court has often indicated that the absence, in one section of a statute, of authority granted in another section enacted at the same time as part of the same law, indicates a Congressional intent not to grant the claimed authority in the silent section. *Cf. Addison* v. *Holly Hill Fruit Products, Inc.*, 322 U. S. 607 (1944); *Crane* v. *Commissioner*, 331 U. S. 1 (1947). If the Administrator believes that the statute should be amended, "he is authorized to call the attention of Congress to the fact," as he has, in fact, done with respect to new chemical food ingredients.* *Cf. F. P. C.* v. *Panhandle Eastern Pipe Line*

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*Congress has had and now has under active consideration bills supported by the Administrator which would extend to him the power to exclude new chemical food ingredients and chemical additives on the basis of a negative finding similar to the power which he enjoys over new drugs. H. R. 2245, 83rd Cong., 1st Sess. (January 29, 1953), *infra*, p. 19a. A similar bill, H. R. 3257, 82d Cong., 1st Sess. (March 15, 1951), was introduced in the 82d Congress. The Select Committee to Investigate the Use of Chemicals in Food Products recommended the adoption of legislation to require testing and approval of chemical additives to foods before marketing, modeled on the procedure now employed with respect to new drugs. H. R. Rep. No. 2356, 82d Cong., 2d Sess. (June 30, 1952). This Commit-

Co., 337 U. S. 498, 515-516 and n. 25 (1949). "It is no warrant for extending a statute that experience may disclose that it should have been made more comprehensive," *Addison* v. *Holly Hill Fruit Products, Inc., supra,* at 617; *cf. United States* v. *Cardiff*, 344 U. S. 174, 175-6 (1952). In approving the Administrator's attempt to graft on to the food standards provision a power not given by Congress to exclude food ingredients on a negative finding, the Court of Appeals has rendered a decision which should be reviewed by this Court.

Instead of meeting these arguments and analyzing this novel problem of statutory construction,* the Court of Appeals rested its decision primarily upon this Court's opinion in *Federal Security Administrator* v. *Quaker Oats Co.*, 318

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tee recommendation responded, in part at least, to a request for legislation by the Commissioner of the Food and Drug Administration. *Hearings Before the House Select Committee to Investigate the Use of Chemicals in Food Products*, 81st Cong., 2d Sess. 33-34 (1950).

An earlier report of the same Committee suggests that Section 401 already "gives the Administrator the power to determine in advance of its use whether a chemical proposed for use in a standardized food is safe." H. R. Rep. 3254, 81st Cong., 2d Sess. 10 (1951). This suggestion, however, gives no support to the assertion that the Administrator may resort to a negative finding to eliminate an established ingredient from a food standard.

*To avoid answering our argument that the Administrator lacks power to exclude a food ingredient on the basis of a negative finding, the Court of Appeals attempted to invade the Administrator's province of finding and weighing facts by implying that the record contains sufficient evidence to justify an affirmative finding of possible harm (R. 3292). But the Administrator did not so find and, in an honest exercise of his office, presumably could not so find. Moreover, this Court has refused to consider whether administrative action could be upheld on another ground if the ground advanced by the Administrator does not support his action. *S. E. C.* v. *Chenery Corp.*, 318 U. S. 80 (1943). See also *Saginaw Broadcasting Co.* v. *F. C. C.*, 96 F. 2d 554, 560-61 (D. C. Cir. 1938), *cert. den.*, 305 U. S. 613 (1938).

U. S. 218 (1943). We respectfully submit that this reliance was misplaced. In the *Quaker Oats* case the Administrator *affirmatively* found that the use of the farina product there at issue "*would tend* to confuse and mislead consumers." *Id.* at 220 (Emphasis supplied). This Court did not approve expulsion from the market because Quaker Oats failed to establish that there was no likelihood that its product would confuse and mislead consumers.

The Court of Appeals also relied heavily upon a distinction between "regulations of legislative type" and a "civil action for damages to be decided in accordance with the preponderance of the evidence" (R. 3295-3296). That distinction—or the distinction between "rule-making" and "adjudication"—does not give an answer to the instant question of statutory power; it merely evades the issue. Even assuming that the proceedings before the Administrator were completely "legislative" in character—an assumption which ignores most of the relevant indicia (including statutory provision for a hearing, cross-examination, detailed findings, and a high degree of judicial review)—the Food, Drug, and Cosmetic Act prescribes standards of fact-finding and standards of review for this type of proceeding which we contend have been ignored. The Administrator's negative finding, as approved by the Court of Appeals, goes beyond the authority granted by the statute. It frustrates the command of Section 701(e) of the Act. It banishes our product from its established market without the benefit of "detailed findings," subject to effective judicial review.

The Court of Appeals, by what we think is erroneous statutory construction, has approved extension of the Administrator's powers far beyond the limits of what Congress

intended. As a result the Court has permitted the Administrator to legislate where Congress did not intend to act and has not yet acted.

II.

The decision of the Court below that a crucial finding of fact made by the Administrator was sustainable even though unsupported by any evidence of record is in conflict with applicable decisions of this Court.

In order to justify his disparate treatment of the Atlas product and the competing mono- and diglycerides, it was necessary for the Administrator to make findings which drew a distinction between the two classes of products.

In his tentative 1950 Order the Administrator proposed to permit the use of mono- and diglycerides at a level of not more than 25% of the shortening content of bread without making any finding as to whether or not they were deceptive (R. 16). The Administrator based his tentative decision to exclude the Atlas products in part on a finding that they served to "soften" bread, an effect which he found to be "deceptive" (R. 8-11). We pointed out in our motion to re-open the record (R. 57-59), and in offers of proof submitted in support thereof (R. 157-161, 171-267), that mono- and diglycerides at the permitted 25% level have the same "softening" effect as Myrj 45; and consequently, if "deception" of consumers was thought to result from the use of Myrj 45 in bread, the same "deception" must result from use of the competing mono- and diglycerides.

The Administrator acknowledged the force of this argument by finding in his final order that use of mono- and diglycerides at "excessive" levels (presumably the 25% level permitted by his proposed order) would produce the

same "softening" effect as Myrj 45 (R. 460). Since the "softening" effect of Myrj 45 was labeled as "deceptive", the Administrator found it necessary to set a "non-deceptive" level of use for the mono- and diglycerides, in terms of a percentage of the shortening content of bread. The level chosen—twenty percent of the shortening content of bread—was designed, as the Court below stated, to "preserve the advantages of shortening while minimizing the dangers of deceptive softening" (R. 3295). We have been able to find but one series of references in the portions of the record cited by the Administrator to a twenty percent level of mono- and diglycerides in shortening as non-deceptive (R. 693-694, 706). That reference is in the testimony of one Bradley. His testimony was modified on cross-examination and ultimately abandoned on redirect (R. 707-709).

In sustaining the Administrator's determination of a non-deceptive level of use for mono- and diglycerides, the Court below was unable to state and did not state that the determination was supported by substantial evidence. In fact, it was supported by no evidence. The Court below was able to say only that "we are not persuaded that the Administrator acted arbitrarily . . . in his determination of an unobjectionable proportion of glycerides" (R. 3295).*

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*The language in the opinion of the Court below on this point may not be entirely clear on first reading. The Court was dealing with two questions at the same time: (1) whether the distinction drawn by the Administrator between the function of the Atlas products and the function of the mono- and diglycerides is supported by substantial evidence, and (2) whether the Administrator's finding as to a "non-deceptive" level of mono- and diglycerides is sustainable. The Court stated its conclusion on both these questions in the same sentence. It concluded that the functional distinction was supported by evidence; but it could only conclude that the setting of a non-deceptive level for

The necessary inference is that the matter was one on which the Administrator's opinion was sufficient, regardless of whether there was any evidence of record to support it. Yet, it was only on the basis of this finding of fact that the Administrator was able to say with any plausibility that there was a difference between the Atlas products and the mono- and diglycerides on the issue of deception. This finding was vital to the distinction drawn; without it, the distinction was an illegal discrimination.* The holding that there need be no evidence to support a finding of fact, the validity of which goes to the root of the administrative action being reviewed, runs directly counter to many forcible expressions by this Court. See, *e. g., S. E. C.* v. *Chenery Corp.,* 318 U. S. 80 (1943); *Universal Camera Corp.* v. *N. L. R. B.,* 340 U. S. 474 (1951). See also *Cream Wipt Food Products Co.* v. *Federal Security Administrator,* 187 F. 2d 789 (3d Cir. 1951).

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mono- and diglycerides was not an arbitrary exercise of the Administrator's judgment.

> "While the description and exposition of the 'shortening' effect of the glycerides in the record is less than one might desire for clarity, we think that at least there is substantial evidence that these additives make bread 'tenderer to the bite'. Moreover, in recognition of this distinction, *the Administrator permitted the use of glycerides only at a stated level which in his judgment would preserve the advantages of shortening while minimizing the dangers of deceptive softening.* Petitioners insist that the evidence relied upon to support this distinction does not do so when correctly analyzed. While this interpretation is arguable, *we are not persuaded that the Administrator acted arbitrarily* either in his contrary interpretation of the evidence or *in his determination of an unobjectionable proportion of glycerides*" (R. 3295, emphasis supplied).

*The emphasis in the record on the question of deception (R. 460-461, 466) shows that if the Administrator could not establish a non-deceptive level for mono- and diglycerides, he could not and would not have admitted them and excluded Myrj 45, merely because of claims that mono- and diglycerides enhance shortening.

III.

Contrary to the plain language of the Food, Drug, and Cosmetic Act, as well as prior decisions of this Court, the Court of Appeals denied an application for leave to adduce additional evidence without independently determining the materiality of that evidence.

Section 701(f)(2) of the Federal Food, Drug, and Cosmetic Act provides that:

> "If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary [now the Administrator], the court may order such additional evidence . . . to be taken before the [Administrator] . . ."

The application contemplated by the statute is addressed to the discretion of the Court and *not* to that of the administrative agency. This provision places upon the Court of Appeals the duty to determine *itself, de novo,* whether or not the additional evidence sought to be adduced is material and whether or not there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator. This statutory duty differs from that of merely determining whether or not the Administrator abused *his* discretion in refusing to receive the additional evidence—a lesser duty of review which exists even in the absence of statute. See *Atchison, T. & S. F. Ry. Co.* v. *United States,* 284 U. S. 248 (1932); *I. C. C.* v. *City of Jersey City,* 322 U. S. 503 (1944). Therefore, as this

Court has held in *N. L. R. B.* v. *Indiana & Michigan Electric Co.*, 318 U. S. 916 (1943), interpreting an identical provision of the National Labor Relations Act, the Court of Appeals must *itself* review the nature of the evidence offered and determine, *itself*, whether such evidence is *material*. See also *Southport Petroleum Co.* v. *N. L. R. B.*, 315 U. S. 100, 104 (1942); *N. L. R. B.* v. *Mexia Textile Mills*, 339 U. S. 563, 569 (1950); *cf. N. L. R. B.* v. *Donnelly Garment Co.*, 330 U. S. 219, 233-236 (1947).

The additional evidence which we sought to have introduced in a reopened hearing included extensive experimental work on the safety of Myrj 45 carried out by the Food and Drug Administration's scientists subsequent to the close of the hearings on September 20, 1949 (R. 37-40, 347-350, 451-455). The Administrator denied our motions when he issued his final order on May 12, 1952 (R. 456-457, 476-484).

In our petition for review, we applied to the Court of Appeals pursuant to Section 701(f)(2) for leave to adduce additional evidence, including evidence of the experimental work conducted on our product by the Administrator's staff (R. 3249). Since the status, methods and results of this experimental work (the elements which would determine their materiality as additional evidence) were not within our direct knowledge, but on the contrary, were peculiarly within the Administrator's knowledge and control, we requested specific information from him concerning them.* He had previously considered these tests sufficiently important to submit information about them to the National Research Council, to aid that body in its considera-

*Reply brief for Petitioner in Court of Appeals, pages 5a-6a. Certified copy lodged with the Clerk of this Court.

tion of problems relating to the use of chemicals in foods. But the Administrator refused us access to the same information on the ground that we might present it to the Court.*

The Administrator's continued refusal of our requests for information about the status of the testing program conducted by his own expert assistants effectively blocked the presentation of the results of these tests to the Court of Appeals.

In the Court of Appeals the Government explained its failure to reopen the record to receive the evidence of the new tests as follows:

> "The argument about alleged tests made by the Food and Drug Administration has considerable superficial appeal. But it must be remembered that the Atlas allegations are based on speculation. *As a matter of fact, after this petition for review was filed, Atlas sought to interrogate the Administrator about the tests.* The Company was told that no tests have been completed that change the picture presented by the existing record. Before the final order issued, the Administrator had before him the Atlas allegation that results of Food and Drug Administration tests were extant. Nevertheless, he denied the motion. *Actually, the Administrator asked the Food and Drug Administration if it had any results of tests that would settle the question of safety. He was informed that the Administration had no such data. The final order was promulgated on the record"* Government's Brief in the Court of Appeals in No. 10,765, pp. 71-72 (emphasis supplied).

On the strength of this representation by the Administrator in his brief, the Court of Appeals concluded that

*Reply brief, page 8a.

"the most recent governmental research is not and does not purport to be decisive as to the safety of the Atlas products and thus did not warrant re-opening the record" (R. 3297). This decision as to the materiality of evidence on the hearsay representation of a party, without independent examination of the evidence, was clearly wrong. At the very least, the Court of Appeals should have required the Administrator to furnish to the Court and to Atlas the evidentiary record of the tests on Myrj 45 conducted in his own laboratories, so that the Court could determine for itself whether this evidence was sufficiently "material" to justify the re-opening of the record.

To the extent that the Court below failed to make an independent evaluation of the additional evidence which we proffered, its decision narrows judicial review of orders issued by several administrative agencies, under a variety of regulatory statutes, since these statutes include provisions as to the taking of additional evidence substantially identical with Section 701(f)(2) of he Food, Drug and Cosmetic Act.*

If the rule of the *Indiana & Michigan Electric Co.* case, *supra,* is to be narrowed, it should not be done *sub silentio* by an intermediate appellate court, but after careful con-

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*Section 5(c) of the Federal Trade Commission Act, 38 Stat. 717, 720 (1914), 15 U. S. C. 45(c); Section 9(a) of the Securities Act of 1933, 48 Stat. 74, 80 (1933), 15 U. S. C. 77i(a); Section 25(a) of the Securities Exchange Act of 1934, 48 Stat. 881, 902 (1934), 15 U. S. C. 78y(a); Section 24(a) of the Public Utility Act of 1935, 49 Stat. 803, 834 (1935), 15 U. S. C. 79(x)(a); Section 322(a) of the Trust Indenture Act of 1939, 53 Stat. 1149, 1175 (1939), 15 U. S. C. 77 vvv(a); Section 42(a) of the Investment Company Act of 1940, 54 Stat. 789, 844 (1940), 15 U. S. C. 80a-42(a); Section 10(e) of the Labor Management Relations Act of 1947, 61 Stat. 136, 148 (1947), 29 U. S. C. 160(e); Section 7(c) of the Judicial Review Act of 1950, 64 Stat. 1129, 1131 (1950), 5 U. S. C. 1037(c).

sideration by this Court, in the light of its effect on a broad area of federal administrative law.

CONCLUSION

The petitioner prays that the writ be granted.

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APPENDIX A

Applicable Provisions of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 *et seq.*, 21 U. S. C. 321(p), 331(a)(b) and (c), 332, 333(a), 334(a) and (d), 341, 342, 343, 346, 351(a), 352(a) and (b), 355, 371.

* * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

* * *

["New Drug"]

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

* * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

* * *

INJUNCTION PROCEEDINGS

SEC. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes", approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 387).

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

* * *

SEIZURE

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, [or while held for sale (whether or not the first sale) after shipment in interstate commerce]* or which may not, under the provisions of sections 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found:

Provided, however, That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations, shall not apply

(1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or

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*Phrase in brackets added by 62 Stat. 582 (1948).

(2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. . . .

* * *

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States . . .

* * *

CHAPTER IV—FOOD

Definitions and Standards for Food

Sec. 401. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container:

Provided, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the pre-

scribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or

(3) if it consists in whole or in art of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406:

Provided, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum and pectin:

Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless its bears a label containing

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count:

Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the

label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless

(1) it conforms to such definition and standard, and

(2) its label bears the name of the food specified in the definition and standard, and insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears

(1) the common or usual name of the food, if any there be, and

(2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings,

other than those sold as such, may be designated as spices, flavorings, and colorings without naming each:

Provided, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact:

Provided, That to the extent that compliance with the rerequirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

* * *

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds

necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

* * *

CHAPTER V—DRUGS AND DEVICES

Adulterated Drugs and Devices

Sec. 501. A drug or device shall be deemed to be adulterated—

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

(3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious sub-

stance which may render the contents injurious to health; or

(4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

* * *

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count:

Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

* * *

NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of

subsection (a). Such person shall submit to the Secretary as a part of the application

(1) full reports of investigations which have been made to show whether or not such drug is safe for use;

(2) a full list of the articles used as components of such drug;

(3) a full statement of the composition of such drug;

(4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and

(6) specimens of the labeling proposed to be used for such drug.

(c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that

(1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

(2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

(3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds

(1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or

(2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

(g) Orders of the Secretary issued under this section shall be served

(1) in person by any officer or employee of the department designated by the Secretary or

(2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Secretary shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial

Code, as amended (U. S. C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia," approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) The Secretary shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

* * *

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Agriculture shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be

contained in other laws of the United States and regulations promulgated thereunder.

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such

order. The summons and petition may be served at any place in the United States. The Secretary, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Secretary based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) The Court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

* * *

Text of H. R. 2245, 83d Congress, 1st Sess., January 29, 1953.

A BILL

To amend the Federal Food, Drug, and Cosmetic Act by providing for the regulation of chemical additives in food.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 201 of the Federal Food, Drug, and Cosmetic Act is amended by adding the following paragraph:

"(q) The term 'chemical additive' means any substance (including products resulting from changes in such substance after use) which (1) is intended for use (A) as a food, or (B) to preserve or alter any food or any characteristic of any food, or (C) as a pesticide or for any other purpose in producing, processing, packing, transporting, wrapping or holding food if such use if likely to result in the contamination of the food; and (2) is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of such substances, as having been adequately tested to show that it is not poisonous or deleterious, or is a poisonous or deleterious substance which is not generally recognized among such experts as having been adequately tested to show that it is safe for an intended use described in this paragraph."

SEC. 2. Section 407 of such Act shall hereafter be designated as section 408.

SEC. 3. Section 301 of such Act is amended by changing "404 or 505" in subsection (d) to "404, 407, or 505"; and "404, 505, 506, 507, or 704" in subsection (j) to "404, 407, 505, 506, 507, or 704".

SEC. 4. Section 304 of such Act is amended by changing "404 or 505" in subsections (a) and (d) to "404, 407, or 505".

SEC. 5. Section 402 (a) of such Act is amended by changing the period at the end to a semicolon and adding: "or (7) if it bears or contains any chemical additive, unless the use of such chemical additive in the quantity present in or on such food has been approved pursuant to section 407."

SEC. 6. The following section shall be added to chapter IV of such Act:

"CHEMICAL ADDITIVES

"SEC. 407. (a) No person shall introduce or deliver for introduction into interstate commerce any chemical additive, unless the use of such chemical additive has been approved pursuant to subsection (d) or (e).

"(b) Any person may file with the Administrator a request for the issuance of an order approving the use of a chemical additive. There shall be submitted to the Administrator as a part of the request (1) reports of investigations which have been made to determine the acute and chronic toxicity and other potentiality for harm of the chemical additive; (2) a statement of the composition of the chemical additive; (3) a description of methods of analysis for the quantitative determination of the chemical additive in or on food, including animal or plant tissues if stored therein; (4) such samples of the chemical additive as the Administrator may require; (5) all directions, recommendations and suggestions proposed for the use of the chemical additive; and (6) if the chemical additive is a poisonous or deleterious substance (A) a statement showing that the chemical additive is required in the production of food, (B) reports of investigations which have been made to show the quantities of the chemical additive, if any, remaining in or on the food, and (C) a description of adequate methods of removal of excessive quantities of the chemical additive remaining in or on the food.

"(c) After the use of a chemical additive has been approved, the applicant may file a supplemental request set-

ting forth any proposed change in the directions, recommendations and suggestions for the use of the chemical additive or in any other information in the original request.

"(d) Unless the Administrator issues a notice of hearing pursuant to subsection (e) prior to the sixtieth day after the date on which a request or supplemental request is filed, the request or supplemental request shall be deemed to have been approved on said sixtieth day for the uses specified; but the Administrator may issue an order approving the request or supplemental request at an earlier date or may postpone the date on which the request or supplemental request shall be deemed to have been approved until such time (not more than one hundred and eighty days after it has been filed) as the Administrator deems necessary to enable him to conduct the necessary study and investigation.

"(e) Unless a request or supplemental request is approved as provided in subsection (d), the Administrator shall give the applicant an opportunity for a hearing for the purpose of determining whether an order shall be issued approving the request or supplemental request. As soon as practicable after completion of the hearing, the Administrator shall notify the applicant of his action in approving or refusing to approve the request or supplemental request. If the Administrator finds that (1) the investigations, reports of which are required to be submitted to him pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show that the chemical additive is not poisonous or deleterious, or if it is, that it is safe and required for its intended use; or (2) the results of such tests show that the chemical additive is poisonous or deleterious, and that it is unsafe or not required for such use or do not show that it is safe and required for such use; or (3) the methods of analysis for the quantitative determination of such chemical additive in or on food, including animal and plant tissues if stored therein, or the methods

of removal of excessive portions, are inaccurate or otherwise inadequate; or (4) he has insufficient information to determine whether the chemical additive is poisonous or deleterious, or if it is, whether it is safe and required for such use, he shall refuse to approve the request or supplemental request. In determining whether to issue an order approving a request or supplemental request for the use of a chemical additive and the quantity of such chemical additive to be permitted in or on any food, the Administrator shall take into account the extent to which such substance is required in or on such food and the other ways in which the consumer may be affected by the same substance or other substances. The Administrator shall make his order, and any order issued under subsection (f), only after a review of the whole record and in accordance with the reliable, probative and substantial evidence, and in any such order shall make detailed findings of the facts on which he based his order. Such orders shall be subject to judicial review in accordance with the provisions of section 701 (f).

"(f) After notice to the applicant and affording him an opportunity for a hearing, the Administrator may issue an order suspending the approval of a request or supplemental request with respect to a chemical additive if he finds that (1) experience in the use of the chemical additive, tests by new methods, or tests by methods not deemed reasonably applicable when the request or supplemental request was approved, show that the chemical additive is unsafe for any use upon the basis of which the request or supplemental request was approved, or (2) the request or any supplemental request contains any untrue statement of a material fact. The applicant may at any time thereafter request an order terminating the suspension and the Administrator, if reasonable grounds therefor are shown, shall make a prompt investigation and afford the applicant an opportunity for a hearing. The Administrator shall terminate the suspension if he finds that adequate measures have been taken to com-

ply with and maintain the provisions of the request or supplemental request.

"(g) The Administrator shall promulgate regulations exempting from the operation of this section chemical additives intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of such chemical additives."

SEC. 7. This statute shall take effect six months after the date of its enactment.